UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

TEVA PHARMACEUTICALS USA, INC., et al.,

Plaintiffs,

-v-

SANDOZ INC., et al.,

Defendants.

09 Civ. 10112 (KBF)

OPINION & ORDER

TEVA PHARMACEUTICALS USA, INC., et al.,

Plaintiffs,

-v-

MYLAN PHARMACEUTICALS INC., et al.,

Defendants.

10 Civ. 7246 (KBF)

KATHERINE B. FORREST, District Judge:

Before this Court are motions to dismiss two nearly identical patent suits brought in 2009 and 2010 by Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd., Teva Neuroscience, Inc., and Yeda Research and Development Co., Ltd. (collectively "Teva" or "plaintiffs"). In December 2009, Teva sued Sandoz Inc.[1] and Momenta Pharmaceuticals, Inc. (collectively "Sandoz" or

[1] Sandoz International GmbH, Sandoz AG, and Novartis AG were also named as defendants but were dismissed in August 2010.

"Sandoz defendants.")[2] In 2010, the same Teva entities sued Mylan Pharmaceuticals Inc., Mylan Inc.,[3] and Natco Pharma. Ltd. (collectively "Mylan" or "Mylan defendants").[4]

Yeda Research and Development Co., Ltd. is the owner, and Teva Pharmaceuticals Industries Ltd. the exclusive licensee, of the four patents-in-suit in both actions: United States Patent Nos. 6,514,938 ("the '938 Patent"), 7,074,580 ("the '580 Patent"), 7,163,802 ("the '802 Patent"), and 7,615,359 ("the '359 Patent"). Together, these patents are referred to as the "Gad Patents."

All four patents relate to a branded glatiramer acetate product marketed under the name Copaxone. (09 Compl. ¶ 24; 10 Compl. ¶ 23.) Copaxone is a drug prescribed to reduce the frequency of relapses in patients with relapsing-remitting multiple sclerosis. (09 Compl. ¶ 25; 10 Compl. ¶ 24.) Both Sandoz and Mylan have filed Abbreviated New Drug Applications ("ANDAs") with the Food and Drug Administration ("FDA") to obtain approval for generic forms of Copaxone that would be competing glatiramer acetate products. (09 Compl. ¶ 26; 10 Compl. ¶ 25.)

In both complaints, Teva alleges that the Mylan and Sandoz defendants have used and will use "technology patented in the four patents-in-suit to characterize the active ingredient of their generic products and to assess whether that active ingredient has the same molecular weight characteristics as glatiramer acetate, the

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[2] Momenta Pharmaceuticals, Inc. ("Momenta") is alleged to have worked in active concert and participations with Sandoz to have made and used Teva's patented markers and processes.
[3] While Mylan Inc. is named as a defendant, plaintiffs do not assert any claims against Mylan Inc. Mylan Inc. is therefore dismissed as a defendant in this lawsuit.
[4] The December 10, 2009 complaint against the Sandoz defendants is referred to herein as "09 Compl." The September 20, 2010 complaint against the Mylan defendants is referred to herein as "10 Compl."

active ingredient of Copaxone." (Mem. Opp'n Defs. [Mylan]'s Mot. Dismiss at 1, 10 Civ. 7246, ECF No. 63 ("Teva Opp'n").)[5]

The patents-in-suit claim polypeptide "markers" and methods for using such markers; the markers are polypeptides that, when used with certain equipment, can measure the molecular weight characteristics of a sample of glatiramer acetate.

Glatiramer acetate, the active ingredient in Copaxone, is a mixture of polypeptides. To show that the active ingredient of their generic products is the "same" as the glatiramer acetate in Copaxone — a showing necessary for the FDA to approve defendants' ANDAs — Mylan and Sandoz must demonstrate that the polypeptides in their products have the same molecular weight characteristics as the polypeptides that constitute glatiramer acetate. (Id. at 4.) As Teva further explains in its briefing:

> One way to measure the molecular weight distribution of the polypeptides in a sample is to run the sample through a size exclusion chromatopgraphic ('SEC') column. Polypeptides of different sizes travel through an SEC at different speeds and therefore come out of the column at different times (referred to as 'retention time'). The retention times of the sample coming out of the column can be correlated with molecular weight by running through the column polypeptides of known molecular weight (called 'markers') and measuring the time it takes for those markers to traverse the column.

Id. at 4-5; see also Teva Pharm. USA, Inc. v. Sandoz, Inc., 876 F. Supp. 2d 295, 324-25 (S.D.N.Y. 2012).

[5] The patented technology at issue is not described in any detail in the complaints. However, the complaints incorporate the patents-in-suit by reference and the descriptions referred to in the parties' submissions are derived from those patents.

The patents-in-suit relate to polypeptide markers developed by Teva "suitable for calibrating chromatographic columns to measure the molecular weight characteristics of glatiramer acetate." (Teva Opp'n 5.) The claimed markers are not themselves drug products, nor do they need approval from the FDA.

In both complaints, the odd numbered counts — I, III, V, and VII — allege that defendants have used the patented products and methods claimed by Teva's patents-in-suit in preparing Mylan and Sandoz's ANDAs for their generic glatiramer acetate products. All defendants have moved to dismiss these counts pursuant to Federal Rule of Civil Procedure 12(b)(6) on the basis that any activities utilizing the patents-in-suit in connection with preparation of an ANDA is protected by the safe harbor provisions of § 271(e)(1).

Both complaints also request declaratory relief in the even numbered counts – II, IV, VI and VIII. Plaintiffs assert that defendants will, in the future, use the claimed technology to market and distribute their generic glatiramer acetate product. Defendants assert that these claims should be dismissed for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) because there is no case or controversy: both Mylan and Sandoz are now utilizing a different technology, they have both committed not to use the technology claimed in Teva's patents-in-suit.[6] (See May 17, 2013 Mylan Letter, 10 Civ. 7246, ECF No. 73 ("Mylan has no intention to make use of the Gad markers in the future."); May 20, 2013 Sandoz Letter, 09 Civ. 10112, ECF No. 96 ("Sandoz further covenants that it

[6] The ANDAs for both Mylan and Sandoz are pending with the FDA. It is unclear when or if they will be approved. Teva's patent exclusivity runs in 2015.

will not reintroduce the use of the accused peptides for production of any product sold prior to the expiration of the Gad patents-in-suit.").)

For the reasons set forth below, the Court hereby GRANTS defendants' motions to dismiss in their entirety.

I. STANDARDS OF REVIEW

A. Rule 12(b)(6)

On a motion to dismiss, the Court accepts as true all well-pleaded factual allegations. See Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). To avoid dismissal, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. In applying that standard, the court accepts as true all well-plead factual allegations, but does not credit "mere conclusory statements" or "threadbare recitals of the elements of a cause of action." Id. If the court can infer no more than "the mere possibility of misconduct" from the factual averments — in other words, if the well-pleaded allegations of the complaint have not "nudged claims across the line from conceivable to plausible," dismissal is appropriate. Twombly, 550 U.S. at 570; Starr v. Sony BMG Music Entm't, 592 F.3d 314, 321 (2d Cir. 2010).

When evaluating the sufficiency of the allegations, courts look not only to the complaint itself, but also to documents attached to it, incorporated by reference in

it, or relied upon by the plaintiff in bringing suit. Rothman v. Gregor, 220 F.3d 81, 88 (2d Cir. 2000).

Finally, in examining the complaint — as well as any documents appropriately considered with it — the Court draws all reasonable inferences in plaintiff's favor. Simon v. KeySpan Corp., 694 F.3d 196, 198 (2d Cir. 2012).

In the instant two cases, the safe harbor protections of § 271(e)(1) are affirmative defenses. Courts may grant motions to dismiss based on an affirmative defense so long as the applicability of the defense is apparent on the face of the complaint or documents incorporated by reference within the complaint. See Staehr v. Hartford Fin. Servs. Grp., Inc., 547 F.3d 406, 425 (2d Cir. 2008) ("Dismissal under Fed. R. Civ. P. 12(b)(6) is appropriate when a defendant raises a statutory bar as an affirmative defense and it is clear from the face of the complaint, and matters of which the court may take judicial notice, that the plaintiffs' claims are barred as a matter of law." (internal quotations omitted)); McKenna v. Wright, 386 F.3d 432, 436 (2d Cir. 2004).

Courts dismiss patent cases when it is clear that the challenged conduct is covered by the statutory safe harbor set forth in § 271(e)(1). See, e.g., Classen Immunotherapeutics, Inc. v. Biogen IDEC, 381 F. Supp. 2d 452, 455-56 (D. Md. 2005).

B. Rule 12(b)(1)

"A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to

adjudicate it." Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000); see also Williams v. Skyline Auto. Inc., 11 Civ. 8318, 2012 WL 1965334, at *2 (S.D.N.Y. May 24, 2012). To survive a Rule 12(b)(1) challenge to the Court's subject matter jurisdiction, the plaintiff must "allege facts that affirmatively and plausibly" suggest that jurisdiction exists. Amidax Trading Grp. v. S.W.I.F.T. SCRL, 671 F.3d 140, 145 (2d Cir. 2011); see also GMA Accessories, Inc. v. Dorfman-Pacific Co., Inc., 11 Civ. 3731, 2012 WL 899385, at *3 (S.D.N.Y. Mar. 16, 2012) (holding that dismissal is proper "when the complaint fails to allege sufficient allegations to support subject matter jurisdiction"). As with motions brought pursuant to Rule 12(b)(6), in the context of a motion to dismiss for lack of subject matter jurisdiction, the Court assumes the facts in a well-drawn complaint to be true and construes all reasonable inferences in the plaintiffs' favor. Amidax, 671 F.3d at 145.

The even numbered counts in both complaints here at issue are brought pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. That act requires that there be an actual controversy between the parties. MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (holding that the type of case or controversy referred to in the Declaratory Judgment Act is the type of case or controversy referred to in Article III of the United States Constitution).

To satisfy the case or controversy requirement, a plaintiff bears the burden of asserting sufficient facts showing that a controversy is definite and concrete — that it is real and substantial. Id. In deciding a motion to dismiss for lack of subject matter jurisdiction, the court may look outside of the pleadings themselves — and

indeed, must do so if "resolution of the proffered factual issue may result in dismissal of the complaint for want of jurisdiction." Robinson v. Malaysia, 269 F.3d 133, 141 n.6 (2d Cir. 2001).

II. DISCUSSION

A. The Statutory Safe Harbor Exception

At its core, this is a case that requires the Court to engage in statutory construction of the safe harbor provision set forth in the Hatch-Waxman Act, codified at 35 U.S.C. § 271(e)(1). This is not a case of first impression. Rather, there are precedents to which each side points supportive of their positions.

As an initial matter, first principles require that the Court begin with the text of the statute itself. Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002). If the meaning of a statute is plain and unambiguous, the Court need do no more than state the obvious. See Robinson v. Shell Oil Co., 519 U.S. 337, 340 (1997); United States v. Ron Pair Enters., Inc., 489 U.S. 235, 240-41 (1989). Whether a statute is ambiguous depends on the language at issue, the context in which it is used, and the overall context and intent of the statute. Robinson, 519 U.S. at 341.

The overall context of the statute at issue is clear. It derived from a congressional intent to adjust for two unintended distortions existing at the time of its enactment that impacted the seventeen-year exclusivity of the patent grant. The first distortion was that the lengthy period that obtaining regulatory approval for certain drugs could absorb several years of the patent grant, resulting in a delay in a patentee being able to reap the financial benefits of innovation for the full

seventeen-year period. The second distortion resulted from a Federal Circuit decision holding that the manufacture, use, or sale of a patented invention during the term of the patent constituted an act of infringement — even if the sole purpose of conducting the tests was to develop information necessary to apply for regulatory approval.[7] In response, in 1984, Congress enacted the Hatch-Waxman Act. Relevant to the case before this Court is the section of the Act which addressed the second distortion.[8] See Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 669-70 (1990).

This is Section 202, codified as 35 U.S.C. § 271(e)(1). That provision currently provides in pertinent part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

35 U.S.C. § 271(e)(1).

Important for the issue before this Court is the definition of the phrase "patented invention" in the statute. It is defined in 35 U.S.C. § 100(a): "When used in this title, unless the context otherwise indicates . . . [t]he term 'invention' means invention or discovery." See Eli Lilly, 496 U.S. at 665.

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[7] See Roche Prods., Inc. v. Bolar Pharm. Co., 733 F.2d 858, cert. denied, 469 U.S. 856 (1984).

[8] The FDA's Abbreviated New Drug Application ("ANDA") requires an applicant to submit studies "to establish that its drug is bioequivalent to the reference drug. The ANDA must also include sufficient information to establish that the generic drug has the same active ingredient as the reference drug." Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1350 (Fed. Cir. 2012), cert. denied, --- S.Ct. ----, 2013 WL 655193 (U.S. June 24, 2013).

In Momenta, the Federal Circuit noted that "Congress could not have been clearer in its choice of words: as long as the use of the patented invention is solely for uses 'reasonably related' to developing and submitting information pursuant to 'a Federal law' regulating the manufacture, use or sale of drugs, it is not an act of infringement." Id. at 1354. The Court found that use of a patented testing process in connection with a generic form of a patented drug was not an act of infringement. Id. at 1357.

The Federal Circuit noted that the FDA had rejected an argument that an applicant had to use the same manufacturing process as the branded manufacturer, duplicate the time consuming clinical trials to prove safety and efficacy, or perform a characterization process that the complaining party conceded was impossible. The FDA stated that it has "broad discretion with respect to the information [it] may consider in making a finding on the 'sameness' of the active ingredient." Momenta, 686 F.3d at 1350.

Momenta bears certain striking similarities to the issues before this Court. That case involved the generic version of Lovenox (enoxaparin), a drug that prevents blood clots. "Enoxaparin is produced by breaking the heparin polysaccharide into smaller pieces . . . . Because the heparin starting material is a diverse set of molecules, enoxaparin is also made up of different chain lengths and disaccharide units corresponding to the diversity in the original mix of heparin molecules." Id. at 1350. Additional diversity in the molecules is also introduced "based on the way the heparin molecule is broken down into the low molecular

weight heparin product." Id. The molecular diversity of the enoxaparin product raised particular issues related to showing bio-equivalence of the generic version to the branded version which had gone through extended clinical trials.[9] Id.

Momenta, along with Sandoz, brought the first generic version of enoxaparin to market. Revenues associated with generic sales amounted to a billion dollars per year. Id. at 1351. When a competing generic manufacturer, Amphastar Pharmaceuticals, Inc., seemed likely to obtain approval, Momenta commenced a patent action.

Momenta is the assignee of a methods patent "for analyzing heterogeneous populations of sulfated polysaccharides, e.g. heparin [and] . . . LMWH [e.g. enoxaparin]." Id. at 1351. Use of these patented methods was one way, but not the only way, to perform quality control testing and show bio-equivalence of the product. Momenta asserted that Amphastar had infringed its patented testing method; it sought and obtained a preliminary injunction. The Federal Circuit vacated the injunction.

Notably, the court found that Amphastar was using Momenta's patented method "as a condition for the post-FDA approval sale of enoxaparin." Id. at 1353. The FDA did not require that Momenta's testing method be used — in fact, a variety of methods were available to show equivalence. Id. Amphastar argued that its testing was protected by the safe harbor provision of § 271(e)(1). In analyzing the statute, the Federal Circuit noted that unlike § 271(e)(2), "Congress did not link

[9]A purpose of the ANDA process is to allow a generic manufacturer to avoid repeating this lengthy clinical trial process; instead it must show bio-equivalence of the same active ingredient. See Andrx Pharm. Inc. v. Biovail Corp., 276 F.3d 1368, 1371 (Fed. Cir. 2002).

the safe harbor to the submission of an application for approval under the [FDA] . . . . We cannot change the statutory language. We will not import the limitation of § 271(e)(2) into § 271(e)(1)." Id. at 1355 (citing Diamond v. Chakrabarty, 447 U.S. 303, 315 (1980)). Thus, the scope of the Hatch-Waxman safe harbor does not stop at activities reasonably related to the development of information submitted in an ANDA. Instead, the safe harbor applies "to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." Id. (quoting the statute).

The Federal Circuit found the information that Amphastar sought necessary both to the continued approval of the ANDA and the ability to market the generic, placing Amphastar's activities within the safe harbor. Id. at 1358. The Court also held:

> The safe harbor's protection is not limited to the dire situation where the patented invention is the only way to develop and submit information. Instead, the safe harbor expressly allows the submitter the freedom to use an otherwise patented means to develop the necessary information demanded by the "Federal law." This makes good sense because it eliminates liability for infringement when that act of infringement is, in effect, required by the federal government as part of the continuing safety and efficacy monitoring of an approved drug.

Id. at 1359. And, "[a]s long as the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor." Id. at 1360 (citing Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205-06 (2005)).

The holding of Momenta — combined with its fact pattern — supports dismissal here. Momenta allows for the elective use of patented technology as long as it serves to produce information required under a federal law. Here, the complaints allege that Sandoz and Mylan have done no more than just that.

Further, Momenta's interpretation of the scope of the safe harbor followed the Supreme Court's clear statement in Merck that the safe harbor provides a wide berth for the use of patented products in activities related to the federal regulatory process. Merck, 545 U.S. at 206-07 (The safe harbor exempts "all uses of patented compounds 'reasonably related' to the process of developing information for submission under any federal law regulating the manufacture, use or distribution of drugs." (emphasis in original) (citing Eli Lilly, 496 U.S. at 674)).

In Merck, the Supreme Court held that use of patented peptides to conduct research not ultimately submitted to the FDA, but which furthered research and led to the development of testing for another drug, fell within the safe harbor. Id. In reversing a jury verdict, the Supreme Court specifically approved a jury instruction with regard to the applicability of the safe harbor defense as follows:

> To prevail on this defense, [petitioner] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [petitioner's] and Scripps' situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question.
>
> Each of the accused activities must be evaluated separately to determine whether the exemption applies.

> [Petitioner] does not need to show that the information gathered from a particular activity was actually submitted to the FDA.

Id. at 200-01.

The Supreme Court's explicit endorsement of this jury instruction further supports dismissal here. If either case went to trial, this jury instruction could leave no doubt as to the outcome based simply on the facts pled in the complaints with all inferences drawn in plaintiffs' favor. Here, the complaints plead that in fact Sandoz and Mylan used the Gad markers to contribute to the generation of information relevant to their ANDAs. (09 Compl. ¶¶ 26-27; 10 Compl. ¶¶ 25-26.) Thus, Supreme Court precedent directly supports the actions of Sandoz and Mylan as falling within the safe harbor.

Prior to the Merck and Momenta decisions, the Federal Circuit reviewed the scope of the safe harbor in Abtox, Inc. v. Exitron Corp., 122 F.3d 1019 (Fed. Cir. 1997). Its findings were consistent with the two later cases. In construing that all classes of medical devices fell within the scope of the safe harbor (not just those subject to FDA approval), the Federal Circuit relied upon the language of the statute and the Supreme Court's broad language in Eli Lilly. The Abtox Court held that § 271(e)(1) requires "only that the otherwise infringing act be performed 'solely for uses reasonably related to' FDA approval . . . . In other words, the statutory language allows [use of data] from the tests for more than FDA approval." Id. at 1030 (citation omitted). And, "as long as the activity is reasonably related to obtaining FDA approval, [defendant's] intent or alternative uses are irrelevant to its qualification to invoke the section 271(e)(1) shield." Id.

The statute and this line of Supreme Court and Federal Circuit cases leave little doubt as to the breadth of the statutory safe harbor. However, plaintiffs assert here that two decisions, a Federal Circuit decision in 2008, Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256 (Fed. Cir. 2008), and a district court decision basing its decision on that case, PSN Ill., LLC v. Abbott Labs., 09 Civ. 5879, 2011 WL 4442825 (N.D. Ill. Sept. 20, 2011), provide that the phrase "patented invention" limits the scope of the safe harbor. The Court does not find these cases to be relevant to the issues before this Court.[10]

Proveris is a case which cannot be separated from its factual context — as noted by the Federal Circuit itself. See id. at 1265 ("For the reasons set forth below, we hold that section 271(e)(1) safe harbor does not immunize the OSA from infringement . . . . [I]nsofar as its OSA device is concerned, Innova is not within the category of entities for whom the safe harbor provision was designed to provide relief." (emphasis added)).

In Proveris, a third party manufacturer, Innovasystems, Inc., was making and selling a product that could be used by generic drug manufacturers to conduct tests to assist in the calibration of drug delivery devices. The devices themselves were patented and did not themselves need FDA approval. Innovasystems asserted that its allegedly infringing activities of manufacturing and selling a patented device, which it neither owned nor was licensed to manufacture and sell, were

[10] Even if Proveris were found to be relevant, the Federal Circuit has instructed that when two cases from the Federal Circuit conflict, the earlier precedent controls until overruled or an en banc decision issues. Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 765 (Fed. Cir.1988). Here, as between Abtox and Proveris, Abtox is the earlier decided.

protected by the safe harbor because its customers' activities would be protected. The Court was unable to separate this blatant commercial use of a patented product by a party not itself engaged in development and submission of information under a federal law. See, e.g., id. at 1264-65. The Court focused its distinction on the phrase "patented invention," stating that the patented testing device was not the type of "patented invention" to which § 271(e)(1) refers. Id. at 1266. This is the language to which the Teva plaintiffs here have attached themselves. They are wrong to do so and read Proveris too narrowly.

The rationale of Proveris is clearly based in statutory interpretation, and the Federal Circuit could just as easily, and perhaps it would have been clearer, to have referred to the language "solely for uses" as it was those uses to which the defendant was putting the patented devices that was objectionable (selling them to others and not itself actually developing any information for submission). When a "patented invention" is not used solely for developing information and submission, that invention in connection with that use is not covered by the safe harbor. The statutory language leaves no doubt as to that result. Thus, the holding of the Proveris Court was correct: "Innova's marketing and sale of its OSA device are not exempted" by the safe harbor. Id. That holding is consistent with the statutory language as well as Supreme Court and Federal Circuit precedent.

The fact that a district court in Illinois has relied on Proveris is of no moment. The decision is either wrong or irrelevant. In terms of relevancy, this Court notes that it is a non-binding case in which the facts were that one competitor

was using the product of another to try to develop its own patented product. The court dismissed the defendant's argument that Proveris should be limited to cases in which potential infringers are commercializing someone else's patented product. PSN, 2011 WL 4442825 at *6. The court disagreed and said the distinction made little sense. In fact, that distinction makes all the sense in the world because of the statutory language referred to above. When one is not using a patent "solely" to develop and submit information, one does not fall within the safe harbor. Commercialization is a square peg in a round hole.

The statutory safe harbor is clear. It applies to precisely that activity alleged here to be infringing. Both the Mylan and Sandoz defendants used the patented product solely for uses reasonably related to the development and submission of information under a federal law. The parties do not dispute that this is the case. Instead, plaintiffs claim only that Proveris has created some sort of opening through which their patented product squeezes: that it does not fall within the definition of "patented invention." As described above, that takes the actual holding in Proveris too far. Supreme Court precedent makes that clear.

Without an exclusion for plaintiffs' patented product not being the type of "invention" that can fall within § 271(e)(1), plaintiffs fail to state a claim for the odd numbered counts in either complaint.

III. THE SUBJECT MATTER JURISDICTION CHALLENGE

This case is not in the same procedural posture that it was when it was filed. Since that time, both Mylan and Sandoz have submitted amended ANDAs that

utilize a different method for demonstrating sameness with the active ingredient of glatiramer acetate used in Copaxone. There is no dispute about this fact. There is also no dispute that if and once an ANDA is approved, the approved party will be required to utilize the process approved. The only processes before the FDA do not involve the Teva-patented product.

In addition, the defendants in both actions have made the following commitments via letters submitted to the Court following oral argument on this motion. Mylan has represented to the Court that it "has no intention to make use of the Gad markers in the future. Mylan represents that it will not use the Gad markers except in the remote and unlikely event that the FDA requires such use, and in the event this occurs, Mylan agrees to provide Teva with notice." (May 17, 2013 Mylan Letter,10 Civ. 7246, ECF No. 73.) Sandoz has represented that if "Sandoz makes any further use of the accused peptides prior to approval of its ANDA, it will inform Teva. Sandoz further covenants that it will not reintroduce the use of the accused peptides for production of any product sold prior to the expiration of the Gad patents-in-suit. This second covenant eliminates the possibility of future infringement alleged in the declaratory judgment counts of the Teva Complaint." (May 20, 2013 Sandoz Letter, 09 Civ. 10112, ECF No. 96.) The Court agrees.

In light of these developments, any case or controversy that may have existed at the outset of these cases when filed has been mooted. There is no case or controversy as to whether either set of defendants would be infringing plaintiffs'

products if or when they commercialize a generic version of glatiramer acetate, when they are not using and have committed not to use plaintiffs' patented product. In such a situation, it would be a waste of judicial and the parties' resources to undertake an exercise that can only result in an advisory opinion. The parties' money and time is better spent elsewhere. See Makarova, 201 F.3d at 113; GMA Accessories, 2012 WL 899385, at *3; MedImmune, 549 U.S. at 127.

IV. CONCLUSION

For all of the reasons set forth above, the motions to dismiss brought by defendants Mylan, Natco, and Sandoz are granted in their entirety.

The Clerk of Court is directed to terminate the motions at 09 Civ. 10112 (ECF No. 81), and 10 Civ. 7246 (ECF Nos. 58 and 60), and to terminate these actions.

SO ORDERED.

Dated: New York, New York
July 15, 2013

KATHERINE B. FORREST
United States District Judge